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(54) EXPANDABLE SUPPORTIVE BIFURCATED ENDOLUMINAL GRAFTS

AUSDEHNBARES, UNTERSTÜTZENDES ZWEIGABELIGES ENDOLUMINALES TRANSPLANTAT

GREFFON DE MAINTIEN ENDOLUMINAL EXTENSIBLE A DEUX BRANCHES

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Description

[0001] This invention generally relates to supportive, endoluminal grafts which have the ability to be delivered transluminally and expanded in place to provide a graft that is endoluminally positioned and placed, with the aid of an appropriate inserter or catheter, and that remains so placed in order to both repair a vessel defect and provide lasting support at the location of the graft.

[0002] EP-A-0551179 discloses a multiple component, expandable, supportive endoluminal graft comprising two expandable, supportive, endoluminal components that are adapted to be deployed individually, side-by-side within a blood vessel, such that each component extends from a point proximal to a bifurcation, across said bifurcated into a respective branch vessel. Each endoluminal component comprises a porous fabric elongate tube which is attached to its proximal end, to an expandable, slotted tubular member. In practice, the components are deployed so that their respective tubular members expand into abutment with one another and with the internal walls of the proximal blood vessel to secure the two components in position.

[0003] Elastomeric vascular grafts are known to be made by various methods. Included are methods which incorporate electrostatic spinning technology such as that described by Annis et al. in "An Elastomeric Vascular Prosthesis", *Trans. Am. Soc. Artif. Intern. Organs,* Vol. XXIV, pages 209-214 (1978) and in U.S. Patent No. 4,323,525. Other approaches include elution of particulate material from tubular sheeting, such as by incorporating salts, sugars, proteins, water-soluble hydrogels, such as polyvinyl pyrrolidone, polyvinyl alcohol, and the like, within polymers and then eluting the particulate materials by immersion in water or other solvent, thereby forming pores within the polymer. Exemplary in this regard is U.S. Patent No. 4,459,252.

[0004] Another approach involves the forming of pores in polymers by phase inversion techniques wherein a solventized polymer is immersed in another solvent and the polymer coagulates while the polymer solvent is removed. Also known are spinning techniques such as those described in U.S. Patent No. 4,475,972. By that approach, a polymer such as a polyurethane in solution is extruded as fibers from a spinnerette onto a rotating mandrel. The spinnerette system reciprocates along a path which is generally parallel to the longitudinal axis of the mandrel and at a controlled pitch angle. The result is a non-woven structure where each fiber layer is bound to the underlying fiber layer.

[0005] Also known are stent devices, which are placed or implanted within a blood vessel or other body cavity or vessel for treating occlusions, stenoses, aneurysms, disease, damage or the like within the vessel. These stents are implanted within the vascular system or other system or body vessel to reinforce collapsing, partially occluded, weakened, diseased, damaged or abnormally dilated sections of the vessel. At times, stents are used to treat disease at or near a branch, bifurcation and/or anastomosis. This runs the risk of compromising the degree of patency of the primary vessel and/or its branches or bifurcation, which may occur as a result of several problems such as displacing diseased tissue, vessel spasm, dissection with or without intimal flaps, thrombosis and embolism.

[0006] One common procedure for implanting a stent is to first open the region of the vessel with a balloon catheter and then place the stent in a position that bridges the diseased portion of the vessel. Various constructions and designs of stents are known. U.S. Patent No. 4,140,126 describes a technique for positioning an elongated cylindrical stent at a region of an aneurysm to avoid catastrophic failure of the blood vessel wall, the stent being a cylinder that expands to an implanted configuration after insertion with the aid of a catheter. Other such devices are illustrated in U.S. Patents No. 4,787,899 and No. 5,104,399. U.S. Patents No. 4,503,569 and No. 4,512,338 show spring stents which expand to an implanted configuration with a change in temperature. It is implanted in a coiled configuration and then heated in place to cause the material of the spring to expand. Spring-into-place stents are shown in U.S. Patent No. 4,580,568. U.S. Patent-No. 4,733,665 shows a number of stent configurations for implantation with the aid of a balloon catheter. U.S. Patent No. 5,019,090 shows a generally cylindrical stent formed from a wire that is bent into a series of tight turns and then spirally wound about a cylindrical mandrel to form the stent. When radially outwardly directed forces are applied to the stent, such as by the balloon of an angioplasty catheter, the sharp bends open up and the stent diameter enlarges. U.S. Patent No. 4,994,071 describes a bifurcating stent having a plurality of wire loops that are interconnected by an elongated wire backbone and/or by wire connections and half hitches.

[0007] Stents themselves often do not encourage normal cellular invasion and can lead to undisciplined development of cells in the stent mesh, with rapid development of cellular hyperplasia. Grafts alone do not provide adequate support in certain instances. U.S. Patent No. 5,653,747 describes grafts that have the ability to carry out dilatation and/or support functions. An expandable tubular support component and an elastomeri graft component are combined into a single device wherein the graft material is secured to either or both of the internal and external surfaces of the expandable support component. The graft material is produced by a spinning technique such as that described in U.S. Patent No. 4,475,972. Also, luminal endoprostheses with an expandable coating on the surface of external walls of radially expandable tubular supports are proposed in U. S. Patents No. 4,739,762 and No. 4,776,337. In these two patents, the coating is made from thin elastic polyurethane, Teflon film or a film of an inert biocompatible material. A. Balko et al., "Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aor-

tic Aneurysm", *Journal of Surgical Research,* 40, 305-309, 1986, and U.S. Patents No. 5,019,090 and No. 5,092,877 mention the possibility to coat stent materials with porous or textured surfaces for cellular ingrowth or with non-thrombogenic agents and/or drugs.

[0008] According to the invention there is provided a multiple-component, bifurcating, expandable, supportive, endoluminal graft comprising:

a plurality of expandable, supportive, endoluminal components that are adapted to be deployed individually at a selected location within a body vessel, each of said supportive, endoluminal components being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;
one of said expandable, supportive, endoluminal components being a trunk component, said trunk component including a tubular supporting member, at least one other of said expandable supportive, endoluminal components being a generally cylindrical supportive leg component; characterised in that said trunk component includes a trunk liner positioned along said tubular supporting member, said trunk liner having a generally cylindrical body portion and at least two leg portions, each said leg portion defining a leg opening; and
said generally cylindrical supportive leg component and one of said leg portions of the trunk component are adapated to be telescopically positioned with respect to each other when said leg component and trunk component are deployed within the body vessel.

[0009] The graft of the present invention is expandable and supportive and may expand from a first diameter to a second diameter which is greater than the first. When it is at its first diameter, the expandable, supportive graft may be a size and shape suitable for insertion into a desired body passageway. The material of the graft may be substantially inert and may comprise a generally cylindrical cover generally over the outside surface and/or inside surface of the supporting component. Preferably, the cover and/or lining is elastomeric and porous to encourage desirable growth of tissue thereto in order to assist in non-rejecting securement into place and avoidance of stenosis development. The porous, elastomeric lining and/or cover material may be elastomeric enough to allow for expansion by up to about 2 to 4 times or more of its unexpanded diameter. Components of the bifurcated, expandable, supportive, endoluminal graft are deployable separately, such that each component can be properly positioned with respect to the other into a desired bifurcated arrangement.

[0010] The endoluminal graft of the present invention may thus combine into a single structure both an expandable, luminal prosthesis tubular supporting component and an elastomeric graft component secured thereto. The expandable supportive luminal graft takes on a bifurcated structure made up of components that are designed to be positioned in a bifurcated manner with respect to each other during deployment or repair and support of vessel locations at or near branching sites. Preferably, the graft component is stretchable or elastomeric and does not substantially inhibit expansion of the tubular support component, while simultaneously exhibiting porosity which facilitates normal cellular growth or invasion thereinto of tissue from the body passageway after implantation.

[0011] Following is a description by way of example only with reference to the accompanying drawings of embodiments of the present invention.

[0012] In the drawings:-

Fig. 1 is a perspective view, partially cut away, of an expandable supportive endoluminal graft construction that can be used for endoluminal bifurcated grafts according to the present invention;
Fig. 2 is a cross-sectional view along the line 2-2 of Fig. 1;
Fig. 3 is a perspective view, partially cut away, of another expandable supportive endoluminal graft construction;
Fig, 4 is a cross-sectional view along the line 4-4 of Fig. 3;
Fig. 5 is a perspective view, partially cut away, of a further expandable luminal graft construction;
Fig. 6 is a cross sectional view along the line 6-6 of Fig. 5
Fig. 7 illustrates a trunk component of a multi-component bifurcated expandable supportive endoluminal graft in accordance with the present invention;
Figs. 8, 9 and 10 illustrate implantation of the trunk component of Figure 7, and its assembly in vivo with two independent, tubular, supportive, leg components to form a bifurcated assembly.
Figs. 11, 12, 13, 14, 15, 16, 17 and 18 illustrate another multi-component bifurcated graft in accordance with the present invention and various stages of its separate, componentwise deployment within a body vessel to repair an aneurysm; Figs. 11 and 12 showing deployment of a bifurcated trunk component; Figs. 13 to 17 showing separate deployment of two tubular branch components; and Fig. 18 showing aneurysm healing and contracting after a time following implantation;
Fig. 19 is a perspective view of a bifurcation trunk component which has a single lumen area opening into a double lumen area;
Fig. 20 is a bottom end view of the bifurcation trunk component of Fig. 19; and
Fig. 21 is a perspective view of another bifurcation trunk component, the single lumen area of which has a section of enhanced hoop strength.

[0013] An expandable supportive luminal graft construction that can be used for a multi-component bifurcated, expandable, supportive endoluminal graft in accordance with the present invention (see below) is generally illustrated in Fig. 1 at 21. This construction includes a braided tubular support component having generally helically wound, flexible strand or wire but are axially displaced from one another, and other of which cross these windings and are also axially displaced with respect to each other. The actual structure can be generally braided as illustrated in Wallsten U.S. Patent No. 4,655,771, or as found in self-expanding braided flat wire WallstentR device. Both a cover 23 and a liner 24 are illustrated in Figs. 1 and 2. Either cover 23 or liner 24 can be omitted if there is no desire to substantially encapsulate the tubular support component 22.

[0014] With more particular reference to the illustrated cover 23 and the liner 24, when included they may be formed by an electrostatic spinning process in this illustrative embodiment. Details regarding electrostatic spinning techniques in general are found in Bornat U.S. Patent No. 4,323,525 and in Bornat European patent publication no. 9,941, as well as in the Annis et al. article discussed hereinabove. With further reference to the application of this technology to the multi-component, bifurcating grafts of the present invention, random pattern filaments are formed and electrostatically directed toward a charged mandrel in order to form a random pattern of electrostatically generally cross-linked filaments which take on the configuration of a mat having a cylindrical shape. The filament diameters are particularly fine, as is the pore size of the mat so constructed. A typical range of filament diameters is about 0.5 micron and about 5 microns, and a typical pore size of the electrostatically spun fiber is between about 3 microns and about 20 microns.

[0015] Liner 24 is formed directly on the rotating mandrel by this electrostatic spinning procedure. Thereafter, one of the tubular support components discussed herein, such as the generally braided tubular support 22, is placed over the liner 24 still on the mandrel. In the case of the tubular support 22 in a form that is not spring loaded, this includes longitudinally extending the tubular support 22, such as by pulling one or both of its ends, which thereby decreases its diameter so that it fits snugly over the liner 24. When the generally braided tubular support 22 is of a spring-into-place type, a hold-down member (such as shown in Figs. 18, 20 and 23) is used to prevent automatic radial expansion prior to deployment. When the expandable supportive graft 21 is to include a cover 23, the mandrel is again rotated, and the electrostatic spinning is again accomplished in order to form the cover 23 directly over the tubular support 22. This will also create some bonding between the thus formed cover 23 and the liner 24 at openings between the strands or wires of the woven tubular support 22 or the like. This bonding can be facilitated by uniformly compressing the outer fibers with a soft silicone roller or sponge such that the still tacky outer fibers bond to the inner fibers thereby encapsulating the tubular support within the graft.

[0016] Bonding may also be achieved in this or other embodiments by heat welding and/or by the use of adhesives such as hot melt adhesives, primers, coupling agents, silicone adhesives, and the like, and combinations of these. Examples include aliphatic polycarbonate urethane hot melts and silicone rubber adhesives.

[0017] It is important to note that each of the cover 23 and the liner 24, when either or both are present, is made of an elastomeric material which retains its compliant properties after construction of the expandable supportive graft 21 is completed. In this regard, the graft itself is also elastomeric and compliant. Accordingly, the graft 21 can be delivered transluminally, such as by being pulled down onto the balloon of a catheter and then percutaneously inserted and positioned to the location where the repair is needed. For a non-spring loaded graft, the balloon is then inflated to longitudinally contract and radially expand the graft 21 into engagement with the vessel walls. Because of the compliance of the cover 23 and/or liner 24, and because of the hoop strength of the braided tubular support 22, the graft 21 will remain in place. In the illustrated graft construction ends 25 of the tubular support are exposed and are not covered by the cover 23. This allows the exposed end portions 25 to directly engage the vessel wall, if desired in the particular application, in order to assist in anchoring the graft 21 in place. Liner 24 also can be sized so as to not cover the exposed ends 25, or it can extend to or beyond the edge of the ends 25 when it is desired to avoid or minimize contact between the tubular support and the blood or other fluid flowing through the vessel being repaired or treated.

[0018] Alternatively, when a braided tubular support such as that illustrated in Figs. 1 and 2 is incorporated into a multi-component, bifurcated graft in a non-spring-loaded form, transluminal delivery can be made by way of a catheter or tool having means for longitudinally compressing the endoprosthesis until it has expanded radially to the desired implanted diameter. Such equipment typically includes a member that engages one end of the endoprosthesis and another member which engages the other end of the endoprosthesis. Manipulation of proximally located controls then effects relative movement of the members toward each other in order to thereby longitudinally compress the endoprosthesis. Delivery tools for spring-loaded grafts include a sleeve that maintains the graft at its compressed diameter until the graft is positioned for deployment such as from the end of an insertion catheter to its auto-expanded state.

[0019] With reference to Figs. 3 and 4, another expandable supportive graft is construction that is suitable for use in a multi-component bifurcating graft according to the present invention is illustrated at 31. The illustrated tubular support component 32 is constructed of sinu-

soidally configured wire helically wound into a tubular shape. General structures of these types are generally discussed in Pinchuk U.S. Patent No. 5,019,090.

[0020] A cover 33 can be positioned over the tubular support 32 and/or a liner 34 can be positioned along its lumen. In this illustrated graft the cover 33 and liner 34 are constructed of porous polymers, the pores thereof having been made by elution or extraction of salts and the like, such as described in MacGregor U.S. Patent No. 4,459,252

[0021] Generally speaking, the porosity is determined by the size of the elutable particles as discussed herein and by the concentration of those particles as a percent by volume of a pre-elution mixture thereof with the polymer of the cover or liner. When a graft 31 having both a cover 33 and a liner 34 is prepared, a mandrel or rod is dipped into a liquid polymer having elutable particles as discussed herein dispersed therewithin. After dipping, the polymer covered rod is contacted with, such as by dipping or spraying, a solvent, for the elutable particles, such as water, thereby forming the eluted porous liner 34. Thereafter, the tubular support 32 is positioned thereover and pressed down into the liner. Then, the rod and the assembly thereon are again dipped into the mixture of polymer and elutable particles, followed by setting and contact with solvent to remove the elutable particles in order to form the eluted porous cover 33. It is also possible to directly extrude the particle-containing polymer into a tubular shape.

[0022] Elutable particles which can be used in the making of the eluted porous cover 33 and liner 34 include salts such as sodium chloride crystals, sodium carbonate, calcium fluoride, magnesium sulfate and other water-soluble materials that are readily dissolved by the utilization of water as an elution medium. Other particles that are soluble in organic solvents and the like can be substituted as desired. Further particles include sugars, proteins, and water-soluble hydrogels such as polyvinyl pyrrolidone and polyvinyl alcohol. Suitable polymer materials are as discussed elsewhere herein, the pore size being on the order of about 10 microns to about 80 microns.

[0023] As with the graft constructions of Figures 1 & 2, when desired, ends 35 of the support component 32 can be exposed either on one or both of its cylindrical faces in accordance with the needs of the particular repair or treatment to be carried out. With this approach, the exposed ends 35 will assist in maintaining the graft 32 in place by mechanical engagement between the exposed ends 35 and the vessel being repaired or treated and/or by tissue ingrowth. The anchoring aspect of the exposed ends of the tubular support can be enhanced by continued radial expansion of the balloon or other deployment means which will permit the exposed ends to expand radially outwardly in an amount somewhat greater than that of the rest of the expandable supportive graft and into the surrounding tissue. It is also contemplated that mechanical means can be used to assist in joining the exposed ends of this or other grafts to the vessel wall. An illustrative example in this regard is the use of transluminally delivered staples which can take on the appearance of rivets. Especially advantageous are staples made of an elastomeric material. Illustrated staples are shown at 36 in Fig. 3. They can be incorporated at other locations as well along the graft. One or more windows 37 can be formed through the cover and/or liner and/or tubular support in order to feed outside branch arteries or other vessels.

[0024] Figs. 5 and 6 illustrate a further expandable supported graft construction generally designated as 41, that can be used in the multi-component, bifurcated grafts according to the present invention. Shown is a mesh tubular support component, generally designated as 42, such as those of the type illustrated in Palmaz U. S. Patent No. 4,733,665. These are non-woven mesh-type cylinders or slotted tubes wherein most or all of the individual components are either integrally joined together such as by welding or are integrally formed from a single tube. The resulting endoprostheses are malleable enough so as to be expandable by a balloon or a catheter. Usually these endoprostheses have particularly high hoop strengths.

[0025] Cover 43 and/or liner 44 are made of polymers rendered porous by phase inversion techniques. In accordance with these techniques, a polymer such as a polyurethane is dissolved in a solvent therefor, for example a water-soluble polar solvent, such as dimethyl acetamide, tetrahydrofuran and the like, in order to form what is known as a lacquer. A mandrel or rod is dipped into the lacquer. Thereafter, the dipped rod is contacted with an inversion solvent, such as by dipping in water or a mixture of alcohol and water. This inversion solvent must readily dissolve the polymer solvent of the lacquer, while at the same time being a poor solvent for the polymer. Under these conditions, the polymer coagulates and the polymer solvent of the lacquer is removed and replaced with the inversion solvent. The inversion solvent pulls the polymer solvent out of the polymer on the rod and forms particularly fine pores having a pore size on the order of about 0.5 micron to about 20 microns. The thus formed liner 44 having phase inversion pores is then dried.

[0026] Next, the tubular support component 42 is secured over the liner 44 and is preferably radially compressed onto and into the liner. Thereafter, the cover 43 having phase inversion pores is formed in accordance with the same phase inversion steps as discussed hereinabove for preparation of the liner 44. If desired, either the liner or the cover can be omitted. Cover 43 and liner 44 are thus formed in accordance with a displacing step wherein precipitating non-solvent molecules are substituted for non-precipitating solvent molecules dispersed throughout the lacquer coating. This procedure develops advantageous elastic characteristics. Further details regarding the phase inversion procedure are found in Lymann et al. U.S. Patent No. 4,173,689.

[0027] A multi-component, bifurcated endoprosthesis or expandable supportive graft in accordance with the present invention is generally designated 81 in Figs. 7 - 10. Separate components are included.

[0028] In this case tubular supporting component(s) are, prior to deployment, separate from a trunk component. In this embodiment, a fully independent tubular supporting component 82 can be located at the trunk position of the graft 81. A bifurcated stretchable wall 83 is in contact with the independent tubular supporting component 82 as either or both of a cover or liner. In addition to being substantially coextensive with the independent tubular supporting component 82 at a trunk portion 84 thereof, the stretchable wall 83 includes at least two generally tubular stretchable branch sleeves 85, 86 which are initially devoid of a supporting component. Separate tubular supporting components 89, 90 (Figs. 9 and 10 are also included.

[0029] Implantation of this bifurcated expandable supportive graft is depicted in Figs. 7, 8, 9 and 10. Dual guidewires 64, 65 can be used to properly position the unexpanded bifurcated graft 81 within the bifurcating vessel as shown in Fig. 7 A balloon catheter 68 or similarly functioning device is inserted into the main body of the device so as to expand the independent tubular supporting component 82 and the trunk portion 84 of the bifurcated stretchable wall 83. This deployment initially secures the bifurcated supporting graft into place at that location of the vessel, as shown in Fig. 8 The balloon catheter is then deflated and removed or positioned for use in the next step.

[0030] A suitable balloon catheter 69 or the like is next used to deploy and expand in place the branch tubular expandable supporting component 89, as illustrated in Fig. 9. A similar step deploys and expands in place the other branch tubular expandable supporting component 90, as generally shown in Fig. 10. The bifurcated stretchable wall 83 and the expandable supporting components may be made with the materials and constructions discussed herein and may be subjected to various treatments as discussed.

[0031] A further multi-component, bifurcated, expandable, supportive, graft in accordance with the present invention is one in which the separate components are each expandable supportive graft members. These separate components are illustrated in Figures 11 - 17 which also illustrate their separate deployment with respect to each other within an aortic trunk. Same is shown in connection with treating an abdominal aorto-iliac aneurysm. The device includes a trunk component 101 designed to extend from below the renal arteries to a location between the proximal neck of the aneurysm and the aorto-iliac bifurcation. It will be understood that this trunk component could also be shorter so that it terminates just below the proximal neck of the aneurysm, or it could be made longer so that it extends closer to the aorto-iliac bifurcation site. In addition, the component bifurcated expandable supportive graft of this embodiment is self-expanding and is deployed by means an introducer containing compressed expandable supportive graft components.

[0032] More particularly, and with reference firstly to Fig. 11, a guidewire 102 is first inserted in accordance with known procedures so as to traverse the aneurysm 103. Next, an introducer, generally designed as 104 having the trunk component therewithin in a radially compressed state is inserted over the guidewire 102. The introducer is maneuvered such that it is properly positioned as desired, in this case at a location distal of the distal end of the aneurysm. Then, the sheath 105 of the introducer is withdrawn, such as by sliding it in a proximal direction while the remainder of the introducer 104 remains in place. As the sheath is withdrawn, the trunk 101 expands, eventually achieving the deployed or implanted position shown in Fig. 12. At this stage, the distal portion 106 of the trunk is well anchored into the blood vessel wall and is suitably deployed.

[0033] Fig. 13 shows an introducer, generally designated as 107, having an independent tubular expandable supportive graft leg component 108 (Fig. 14 radially compressed therewithin. In this illustrated embodiment, this leg component is an iliac component of the bifurcated supportive graft being assembled within the body vessel. The introducer 107 is advanced until this iliac component is moved into a leg 109 of the already deployed trunk component 101. This positioning is illustrated in Fig. 14. It will be noted that the iliac tubular supportive graft component 108 extends from well within the leg 109 to a location proximal of the aneurysm in the iliac artery 110.

[0034] In a next step, a guidewire 111 is passed through the appropriate vessel to iliac artery 112 until it crosses the aneurysm 103, while passing through the other leg 113 of the deployed trunk component 101. Introducer generally designated as 114 is advanced over the guidewire 111 and into leg 113. Introducer 114 contains another tubular supportive graft leg component 115 (Fig.17), which is another iliac component. With the introducer 14 removed, the previously radially compressed iliac component 115 expands radially and is deployed. At this stage, the entirety of the bifurcated endoprosthesis or expandable supportive graft in accordance with this embodiment is fully deployed and assembled together.

[0035] Fig. 18 shows a typical aneurysm repair as discussed herein after a lapse of time. The aneurysm eventually heals and contracts as generally shown at 116. Blood flow is, of course, through the implanted bifurcated component endoprosthesis from the abdominal aorta 117 and to both of the iliac arteries 110 and 112.

[0036] It will be noted that it is not required to actually attach the trunk component 101 and the tubular components 108, 115 together. In other words, these components are generally telescopically positioned with respect to each other. This telescopic feature allows some slippage between the trunk component and the tubular

leg components, thereby providing a telescopic joint which is a slip bearing. It will be appreciated that it is generally desirable to firmly anchor portions of the bifurcated endoprosthesis within healthy vessel wall tissue. This can be achieved by the hoop strength of the supportive graft or by taking measures to enhance hoop strength at its ends, or by providing grasping structures such as hooks, barbs, flared ends and the like. During pulsetile blood flow and possibly during exercise by the person within whom the endoprosthesis is implanted, tension and elongation forces are imparted to the endoprosthesis. In structures that do not have a telescopic joint or some other means to relieve the stress developed by this tension, a considerable amount of stress can be placed on the anchoring sites and/or the attachment components, potentially allowing for dislodgement at the anchoring sites or breakage of attachment components.

[0037] Fig. 19 illustrates a trunk component 101a. It includes a common trunk portion 118 and a bifurcated portion, generally designated as 119. The bifurcated portion includes the legs 109 and 113. Trunk component 101a includes a stent or tubular supporting component 121, as perhaps best seen in Fig. 27. Also included is a liner, generally designated as 122. This liner 122 has a body portion 123 and the legs 109 and 113 which take on a combined configuration resembling a pair of pants.

[0038] Each leg 109, 113 is secured to the generally tubular stent component 121 at outside portions thereof, particularly at adhesion zones 124 and 125. The remainder of the leg portions 109 and 113 are not so bonded to the stent portion 121. This facilitates formation of the leg portions, which are typically pinched along the length of the legs in order to form an internal seam 126. Leg openings 127 and 128 are thereby generally defined between this seam 126 and the adhesion zones 124 and 125.

[0039] In Fig. 21 means are included in the trunk component 101b which provides enhanced securement upon implantation. A stent component 129 is included which has a substantially higher pitch angle (for example, between about 140° and 180°) than does the stent portion 121b therebelow within which the legs are positioned (for example, at a pitch angle of between about 70° and 90°). This higher pitch angle zone imparts a greater hoop strength upon deployment than does the stent 121 of the trunk component 101a. A barb 130 is also shown in order to further assist in securement of the endoprosthesis to the artery wall. When desired, the barb-type of structure can be a backing ring and barb formed out of the stent strand during its formation into the cylindrical supportive member.

[0040] Any of the various expandable, supportive endoluminal graft constructions discussed or referred to herein before can be used in order to construct multi-component bifurcated grafts in accordance with this embodiment. Other modifications may also be incorporated, including tubes having stepped diameters or conical ends. The stent component can be made with flat wires or with pairs of wires or multifilament wires. They can incorporate balloon expandable stents, self-expanding stents, and combinations of balloon expandable stents and self-expanding stents. Use can be made of ancillary equipment such as endoluminal stapling devices or suturing devices in order to facilitate securement at the aneurysm neck, for example. Also, a portion of the stent component without a liner component or the like thereon can project at the proximal end of the endoluminal component, such as at a location which would be above the renal arteries. The objective is also to help to secure the device in place.

[0041] A preferred use for the multi-component bifurcating endoluminal grafts discussed herein is for insertion into a branching blood vessel. Same is typically suitable for use in the coronary vasculature (the right, left common, left anterior descending, and circumflex coronary arteries and their branches) and the peripheral vasculature (branches of the carotid, aorta, femoral, popliteal arteries and the like). These multi-component bifurcated devices are also suitable for implantation into other branching vessels such as in the gastrointestinal system, the tracheobronchial tree, the biliary system and the genitourinary system.

[0042] It will be appreciated that the multi-component, bifurcated, expandable supportive grafts in accordance with the present invention will dilate and/or support blood vessel lesions and other defects or diseased areas, including at or in proximity to sites of vascular bifurcation, branches and/or anastomoses. The expandable supportive graft is an integral structure that incorporates the expandable support component into the wall or walls of the elastomeric graft. Covers and/or linings that make up the grafts interface with the body components that facilitate normal cellular invasion with stenosis or recurrent stenosis when the graft is in its expanded, supportive orientation. The graft material is inert and biocompatible. The expandable supportive graft can be expanded from a smaller diameter insertion configuration to a larger diameter implantation configuration by the application of radially outwardly directed forced provided by expanding the endoprosthesis with a balloon catheter, using an ejection tube that allows a spring-into-place structure to be deployed from the end of a catheter into its expanded configuration, or by using a support component made of certain alloys exhibiting thermotransition characteristics by which they expand when heated, for example.

[0043] In addition to the support component structures illustrated herein, support structures include others having spring characteristics and those having a coil with circumferentially oriented fingers such as shown in Gianturco U.S. Patent No. 4,800, 882,

[0044] Materials include, either alone or in combination, metals or metal alloys, polymers, carbon and ceramics. Exemplary metallic members include stainless steel, titanium, tantalum, Nitinol, Elgiloy (trade name)

and NP35N (trade designation), which can provide desired degrees of springiness, malleability and/or response to temperature changes. Exemplary polymers include polyurethanes, silicone rubbers, polyether sulfones, fluoroelastomers, polyimides, polycarbonates, polyethylenes, polylactic acid, polyglycolic acid, polyacrylates, and the like and combinations and copolymers thereof which provide a variety of abilities to bioabsorb or biodegrade or to be totally inert. Any of a variety of these endoprostheses can be combined with any of a variety of the graft cover and/or liner configurations in order to tailor the expandable supportive graft to meet specific needs. Also, combinations can be obtained, such as providing phase inversion pores and salt elution pores on different locations of the graft component to take advantage of the pore size difference between these two types of graft techniques and/or to provide better tissue growth at one location than at another.

[0045] With reference to the material out of which the cover and/or liner of the grafts in accordance with the present invention are made, the material must be stretchable so that it will follow the movement of the endoprosthesis between its fully collapsed and expanded or implanted configurations. Polyurethanes are preferred. Particularly preferred is an especially crack-resistant, elastomeric and pliable polycarbonate urethane as described in Pinchuk U.S. Patents No. 5,133,742 and No. 5,229,431, available from Corvita Corporation under the CORETHANE® trademark. Also suitable are polycarbonate polyurethane covers and liners coated with a thin layer of silicone rubber material as described in Pinchuk U.S. Patent No. 4,851,009.

[0046] In addition, various surface treatments can be applied to render the surfaces of the expandable supported graft more biocompatible. Included are the use of pyrolytic carbon, hydrogels and the like. The surface treatments can also provide for the elution or immobilization of drugs such as heparin, antiplatelet agents, antiplatelet-derived growth factors, antibiotics, steroids, and the like. Additionally, the coating and/or liner can be loaded with drugs such as those discussed herein, as well as lytic agents in order to provide local drug therapy.

[0047] The multi-component, bifurcated graft of the present invention is capable of being tailored to meet specific needs, depending upon the particular defect or diseases being addressed, such as occlusion, stenosis, aneurysm, arteriovenosis fistula, trauma and the like, as well as upon the anatomy of the vessel. For example, it may be desirable to have a supporting component at locations other than throughout the entirety of a graft component as specifically illustrated in Figs. 1 through 4 hereof. It is possible to provide an expandable graft component having its supportive property emanating from one or more supporting components, while thereby providing an adjoining graft cylindrical portion which is supported primarily by its close proximity to a supporting component which can be presented at one end, both ends, or spaced along the expandable supportive graft component. Such a structure is generally illustrated in Fig. 5, wherein an adjoining graft cylindrical portion 71 is positioned between a first supporting component 72 and another or second supporting component 73. An expandable supportive component may thus have the tailorability advantage of being able to vary the configuration, structure and properties of the supporting component or components of the graft. These various properties allow the expandable supportive graft component to be tailored in accordance with particular needs of the disease, defect or damage being treated. For example, support maybe particularly desirable at one location being treated, while a less rigid supportive area is needed at another, generally adjoining location.

[0048] It may also be desirable to incorporate a radiopaque marker in the endoluminal graft specifically in the area of the trunk component defining the bifurcation. The purpose of such a marker is to allow one well versed in the art of implanting these devices to see, under angiography, where the bifurcation is precisely located so as to deploy the leg components within the trunk sockets provided. The radiopaque marker may be in the form of a metallic powder, such as bismuth subcarbonate, tantalum, tungsten, platinum, gold, barium sulfate and the like, dispersed in a binder such as silicone rubber, polyurethane, epoxy and the like, wherein the binder containing the metal powder is painted or printed onto the graft in the desired location. Alternatively, radiopaque sutures or wires can be sewn into the graft at the bifurcation to allow visualization of the device. Similarly, the proximal ends of the leg endoluminal grafts can be painted, printed or sewn with similar markets to aid in visualizing and placing the leg stents during deployment.

Example I

[0049] A bifurcated, aortic, expandable, supportive, endoluminal graft is made in the following manner. An aortic, trunk, supportive, endoluminal graft is fabricated using a 16mm diameter, 12cm long support component. First, a 16mm mandrel is rotated on a spinning machine at 500rpm, and a spinnerette with 30 orifices reciprocated along the axis of the mandrel at 13.8 inches/second (35cm/second). Polycarbonate urethane, in dimethyl acetamide solution (45% solids) is extruded from the spinnerette at 0.123 ml/min and would onto the rotating mandrel such that the fibres form a 50° pitch angle in relation to the axis of the mandrel. The environment in the spinning chamber is controlled such that sufficient solvent from the urethane solution evaporates of during spinning to enable the fibres to bond to underlying fibres during each transverse of the spinnerette. The thus formed spun polycarbonate urethane mesh has a length of about 16cm, is removed from the machine on the mandrel and is cured at 110°C for 16 hours. A supporting component is sheathed over the mesh still on the mandrel with a 4cm excess length of tubular mesh protruding beyond the supporting component. Another 10

passes of polycarbonate urethane were spun over the tubular mesh and support componenting, but not over 4cm excess length of the internal tubular mesh, and the fibres, while still wet, were immediately pressed through the interstices of the supporting component with a silicone rubber sponge, such that the fibres bonded to the underlying fibres of the urethane mesh, thereby capturing the supporting component within the urethane wall. The assembly was then cured for an additional 3 hours at 110°C., after which the assembly was removed from the mandrel. The supportive endoluminal graft formed in this manner has fibre diameters of 10 to 20μ and pore sizes ranging from 10 to 60μ. The excess tubular mesh which protrudes from one side of the assembled endoprosthesis is then slit and sewn down the centre such that the tube is bifurcated into two smaller tubes, thereby resembling a pair of short pants.

[0050] The aortic trunk endoprosthesis is pulled down and sheathed on an introducer catheter, maneuvered into the aorta of a dog, via the dog's femoral artery for deployment in the abdominal aorta. Two smaller stents, of 8mm diameter are also pulled down onto introducer catheters and maneuvered, through each femoral artery for deployment into the "pant legs" of the aortic trunk. The resultant multi-component, bifurcated, endoprosthesis for limiting further dilation of an abdominal-iliac aneurysm.

Example II

[0051] A bifurcated, expandable, supportive endoluminal graft is provided for deployment within and repair of aorto-iliac aneurysms. A generally tubular metallic stent of the self-expandable type is adhered to the outside of a porous spun liner as follows. The graft is wound or spun from filaments deposited onto a rotating mandrel in order to form a cylindrical graft having crossing strands generally adhered together. The resulting inner liner, after it is dried, has the stent component placed over it. Then, an area of the stent is masked, such as with a piece of tape, at the location where an internal seam is to be positioned in the trunk component of the supportive endoluminal graft. The masking can take on a shape on the order of the triangular areas illustrated in Fig. 20 with the upper apex forming the "crotch" of the "pants". Additional fibers are then spun over the entire stent and pressed through the stent intersticies to be certain that the stent is secured to the liner. This continues until all areas of the stent are well-bonded except for the masked area. After removal of the mandrel and of the masking material, the initially formed inner liner is free to be pinched along its length and sutured, sewed and/or glued and the like to form two distinct leg portions and a trunk portion of the liner. The resulting trunk component is as generally shown in Figs. 19 and 20.

[0052] The leg components of the bifurcated, expandable, supportive, endoluminal graft in accordance with this Example are individually made in a similar manner. The liner is formed by spinning compliant fibers over a rotating mandrel, a tubular stent component is positioned thereover and secured in place, and additional fibers are wound with the rotating mandrel. The stent is thus encapsulated between the liner fibers and the cover fibres preferably with the aid of a soft roller or sponge to force the cover strands into the intersticies of the stent component and securement to the underlying liner fibres. After removal from the mandrel, the resulting tubular supportive graft component, suitable for use as both the iliac components, is trimmed to proper length.

Claims

1. A multiple-component bifurcating, expandable, supportive, endoluminal graft comprising:

   a plurality of expandable, supportive, endoluminal components that are adapted to be deployed individually at a selected location within a body vessel, each of said supportive, endoluminal components being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;
   one of said expandable, supportive, endoluminal components being a trunk component (82-85; 101), said trunk component including a tubular supporting member (82; 121), at least one other of said expandable, supportive, endoluminal components being a generally cylindrical supportive leg component (89, 90; 108, 115); characterised in that said trunk component includes a trunk liner (83; 122) positioned along said tubular supporting member, said trunk liner having a generally cylindrical body portion (84; 123) and at least two leg portions (85, 86; 109, 113), each said leg portion defining a leg opening (127, 128); and
   said generally cylindrical supportive leg component (89, 90; 108, 115) and one of said leg portions (85,86; 109, 113) of the trunk component are adapted to be telescopically positioned with respect to each other when said leg component and trunk component are deployed within the body vessel.

2. A supportive endoluminal graft in accordance with claim 1,
   characterised in that said generally cylindrical supportive leg component (89, 90; 108, 115) has an end portion which, when deployed, is positioned within said leg opening (127, 128) of the trunk component.

3. A supportive endoluminal graft in accordance with claim 1 or claim 2,
   characterised in that said plurality of expandable

supportive endoluminal components (82-85, 89,90; 101, 109, 113) are self-expanding.

4. A supportive, endoluminal graft in accordance with claim 1 or claim 2,
characterised in that said plurality of expandable, supportive, endoluminal components are adapted to be deployed by a radially expandable device (69; 104, 107, 114).

5. A supportive, endoluminal graft in accordance with any of claims I to 4, characterised in that said generally cylindrical, supportive leg component includes a generally cylindrical supporting member and a generally cylindrical liner secured thereaiong

6. A supportive endoluminal graft in accordance with any of claims 1 to 5,
characterised in that said trunk liner (83; 122) is a stretchable wall of essentially inert biocompatible material, said stretchable wall being attached to a portion of the internal surface of the trunk component tubular supportive member (82; 121) said stretchable wall having a diameter size that expands with said trunk component tubular supportive member.

7. A supportive endoluminal graft in accordance with claim 5,
characterised in that said liner of the generally cylindrical supportive leg component is a stretchable wall of essential inert biocompatible material, said stretchable wall being applied onto at least the internal surface of the generally cylindrical tubular supporting member of the leg component.

8. A supportive endoluminal graft in accordance with any of claims 1 to 7,
characterised in that said leg portions (85, 86; 109, 113) of the trunk liner extend longitudinally beyond said tubular supportive member of the trunk component.

9. A supportive endoluminal graft in accordance with claim 8,
characterised in that said leg portions are separated from each other.

10. A supportive endoluminal graft in accordance with any of claims 1 to 7,
characterised in that said leg portions of the trunk liner are longitudinally generally coextensive with said tubular supportive member of the trunk component.

11. A supportive endoluminal graft in accordance with claim 10,
characterised in that an outside section (124,125) of each of said leg portions of the trunk liner (122) is secured to said tubular supportive member (21) while inside sections of each of said leg portions are secured to each other along an internal seam (126).

12. A supportive endoluminal graft in accordance with any of claims 1 to 11, characterised in that said generally cylindrical supportive leg component (89,90; 108,115), when deployed, is telescopically slidably positioned within one of said leg portions (85,86; 109,113) of the trunk component.

13. A supportive endoluminal graft in accordance with claim 5,
characterised in that said liner of the leg component and said trunk liner are each of stretchable wall made from a porous elastomeric material that provides a structure which allows normal cellular invasion thereinto from the body vessel when implanted therewithin.

14. A supportive endoluminal graft in accordance with claim 13,
characterised in that said porous elastomeric material of each stretchable wall is an elastomeric polymer.

15. A supportive endoluminal graft in accordance with claim 13,
characterised in that said porous elastomeric material of said stretchable wail is a polycarbonate urethane.

16. A supportive endoluminal graft in accordance with claim 13,
characterised in that said porous elastomeric material is coated with a thin layer of silicone rubber.

17. A supportive endoluminal graft in accordance with claim 5,
characterised in that said trunk liner and said liner of the leg component are each of stretchable wall along the internal surface and the external surface of each supportive member.

18. A supportive endoluminal graft in accordance with any of claims 1 to 7 or 13 to 17, characterised in that an exposed longitudinal end of said tubular supportive component extends longitudinally beyond and is not completely covered by said liner.

19. A supportive endoluminal graft in accordance with claim 17,
characterised in that said tubular supportive member has a plurality of open areas therealong, and said stretchable wall along said external surface of the tubular supporting member is bonded to said stretchable wall along said internal surface of the

tubular supporting member at locations defined by said open areas of the tubular supporting member.

20. A supportive endoluminal graft in accordance with any of claims 1 to 19, wherein said tubular supporting member has a plurality of open areas therealong, and an attachment component passes through one of said open areas of said tubular supporting member.

21. A supportive endoluminal graft in accordance with any of claims 1 to 20, characterised in that said tubular supporting member (82; 121) includes a plurality of wire strands with open areas therebetween.

22. A supportive endoluminal graft in accordance with claim 21,
characterised in that said wire strands of the tubular supporting member (82;121) are generally sinusoidally configured wire that is helically wound into the tubular supporting member, said wire defining therebetween said open areas of the tubular supporting member.

23. A supportive endoluminal graft in accordance with claim 21,
characterised in that said wire strands of the tubular supporting member are shaped as intersecting elongated lengths integral with each other and defining said openings therebetween to form a mesh-shaped tubular supporting member.

24. A supportive endoluminal graft in accordance with any of claims 1 to 23, characterised in that the endoluminal graft comprises a surface treatment for biocompatibility or drug therapy.

25. A supportive endoluminal graft in accordance with any of claims 1 to 24, characterised in that said trunk component includes a projecting securement member (130).

26. A supportive endoluminal graft in accordance with claim 1,
characterised in that said trunk component (82-85) has an internal surface, an external surface spaced outwardly from and shaped complementarily with said internal surface, and a network of land areas with open areas defined therebetween,

said trunk component liner (83) is a stretchable wall of essentially inert biocompatible material, said stretchable wall being applied to at least one of said internal surface and said external surface of the tubular supporting member, said stretchable wall having an extension portion that extends beyond said tubular supporting component thereof; and

said extension portion of the stretchable wall is branched into at least two generally tubular leg portions (85,86) of stretchable wall material, each said leg portion being sized and shaped to receive a said generally cylindrical supportive leg component (89,90).

27. A multi-component, bifurcating, expandable, supportive, endoluminal graft as claimed in any preceding claims, characterised in that said trunk liner (122) is secured to said tubular supporting member (121) and is pinched along its length and sutured, sewn and glued to form two distinct leg portions (109,113).

Patentansprüche

1. Ein verzweigendes, expandierbares, stützendes, endoluminales Implantat aus mehreren Komponenten umfassend:

eine Vielzahl von expandierbaren, stützenden, endoluminalen Komponenten, die angepaßt sind, individuell an einem ausgewählten Ort innerhalb eines Blutgefäßes eingesetzt zu werden, wobei jede der stützenden, endoluminalen Komponenten radial komprimierbar sind zum endoluminalen Einfügen, und radial expandierbar zum Einsatz an einem gewünschten Ort innerhalb eines Blutgefäßes;
wobei eine der expandierbaren, stützenden, endoluminalen Komponenten eine Stammkomponente (82 - 85; 101) ist, wobei die Stammkomponente ein röhrenförmiges Stützteil (82; 121) beinhaltet, wobei wenigstens eine andere der expandierbaren, stützenden, endoluminalen Komponenten eine im allgemeinen zylindrische, stützende Beinkomponente (89, 90; 108, 115) ist; dadurch gekennzeichnet, daß die Stammkomponente eine Stammauskleidung (83; 122) beinhaltet, welche entlang des röhrenförmigen Stützteils positioniert ist, wobei die Stammauskleidung einen im allgemeinen zylindrischen Körperabschnitt (84; 123) aufweist und wenigstens zwei Beinabschnitte (85, 86; 109, 113), wobei jeder der Beinabschnitte eine Beinöffnung (127, 128) definiert; und
wobei die im allgemeinen zylindrische, stützende Beinkomponente (89, 90; 108, 115) und einer der Beinabschnitte (85, 86; 109, 113) der Stammkomponente angepaßt sind, um teleskopisch in Bezug zueinander positioniert zu werden, wenn die Beinkomponente und die Stammkomponente innerhalb des Blutgefäßes eingesetzt sind.

2. Ein stützendes, endoluminales Implantat gemäß

Anspruch 1, dadurch gekennzeichnet, daß die im allgemeinen zylindrische, stützende Beinkomponente (89, 90; 108, 115) einen Endabschnitt aufweist, welcher, wenn er eingesetzt ist, innerhalb der Beinöffnung (127, 128) der Stammkomponente positioniert wird.

3. Ein stützendes, endoluminales Implantat gemäß Anspruch 1 oder Anspruch 2, dadurch gekennzeichnet, daß die Vielzahl von expandierbaren, stützenden, endoluminalen Komponenten (82 - 85, 89, 90; 101, 109, 113) selbstexpandierend sind.

4. Ein stützendes, endoluminales Implantat gemäß Anspruch 1 oder Anspruch 2, dadurch gekennzeichnet, daß die Vielzahl von expandierbaren, stützenden, endoluminalen Komponenten angepaßt sind, um durch eine radial expandierbare Vorrichtung (69; 104, 107, 114) eingesetzt zu werden.

5. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die im allgemeinen zylindrische, stützende Beinkomponente ein im allgemeinen zylindrisches, stützendes Teil beinhaltet und eine im allgemeinen zylindrische Auskleidung, die daran entlang befestigt ist.

6. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß die Stammauskleidung (83; 122) eine dehnbare Wand aus im allgemeinen inertem, biokompatiblem Material ist, wobei die dehnbare Wand an einem Abschnitt der inneren Oberfläche des röhrenförmigen Stammkomponenten-Stützteils (82; 121) angebracht ist, wobei die dehnbare Wand eine Durchmessergröße aufweist, die mit dem röhrenförmigen Stammkomponenten-Stützteil expandiert.

7. Ein stützendes, endoluminales Implantat gemäß Anspruch 5, dadurch gekennzeichnet, daß die Auskleidung der im allgemeinen zylindrischen, stützenden Beinkomponente eine dehnbare Wand aus im allgemeinen inertem, biokompatiblem Material ist, wobei die dehnbare Wand wenigstens an der inneren Oberfläche des im allgemeinen zylindrischen, röhrenförmigen Stützteils der Beinkomponente angebracht ist.

8. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß die Beinabschnitte (85, 86; 109, 113) der Stammauskleidung sich longitudinal über das röhrenförmige Stützteil der Stammkomponente erstrecken.

9. Ein stützendes, endoluminales Implantat gemäß Anspruch 8, dadurch gekennzeichnet, daß die Beinabschnitte getrennt voneinander sind.

10. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß die Beinabschnitte der Stammauskleidung sich longitudinal im allgemeinen gemeinsam mit dem röhrenförmigen Stützteil der Stammkomponente erstrecken.

11. Ein stützendes, endoluminales Implantat gemäß Anspruch 10, dadurch gekennzeichnet, daß ein Außenbereich (124, 125) von jedem der Beinabschnitte der Stammauskleidung (122) an dem röhrenförmigen Stützteil (21) befestigt ist, während Innenbereiche von jedem der Beinabschnitte entlang einer Innennaht (126) aneinander befestigt sind.

12. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, daß die im allgemeinen zylindrische, stützende Beinkomponente (89, 90; 108, 115), wenn eingesetzt, teleskopisch gleitend innerhalb einem der Beinabschnitte (85, 86; 109, 113) der Stammkomponente positioniert ist.

13. Ein stützendes, endoluminales Implantat gemäß Anspruch 5, dadurch gekennzeichnet, daß die Auskleidung der Beinkomponente und die Stammauskleidung jeweils aus einer dehnbaren Wand bestehen, hergestellt aus porösem, elastomerem Material, das eine Struktur vorsieht, welche darein einen normalen Zelleneinfall vom Körpergefäß erlaubt, wenn darin implantiert.

14. Ein stützendes, endoluminales Implantat gemäß Anspruch 13, dadurch gekennzeichnet, daß das poröse, elastomere Material jeder dehnbaren Wand ein elastomere Polymer ist.

15. Ein stützendes, endoluminales Implantat gemäß Anspruch 13, dadurch gekennzeichnet, daß das poröse, elastomere Material der dehnbaren Wand ein Polycarbonat-Urethan ist.

16. Ein stützendes, endoluminales Implantat gemäß Anspruch 13, dadurch gekennzeichnet, daß das poröse, elastomere Material beschichtet ist mit einer dünnen Schicht aus Silikongummi.

17. Ein stützendes, endoluminales Implantat gemäß Anspruch 5, dadurch gekennzeichnet, daß die Stammauskleidung und die Auskleidung der Beinkomponente jeweils aus einer dehnbaren Wand entlang der inneren Oberfläche und der äußeren Oberfläche jedes der Stützteile bestehen.

18. Ein stützendes, endoluminales Implantat gemäß ei-

nem der Ansprüche 1 bis 7 oder 13 bis 17, dadurch gekennzeichnet, daß ein exponiertes longitudinales Ende der röhrenförmigen, stützenden Komponente sich longitudinal über die Auskleidung erstreckt und nicht komplett durch die Auskleidung bedeckt ist.

19. Ein stützendes, endoluminales Implantat gemäß Anspruch 17, dadurch gekennzeichnet, daß das röhrenförmige, stützende Teil eine Vielzahl von offenen Bereichen dort entlang aufweist, und daß die dehnbare Wand entlang der äußeren Oberfläche des röhrenförmigen Stützteiles an der dehnbaren Wand entlang der inneren Oberfläche des röhrenförmigen Stützteiles an Orten verbunden ist, die durch die offenen Bereiche des röhrenförmigen Stützteils definiert sind.

20. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 19, wobei das röhrenförmige Stützteil eine Vielzahl von offenen Bereichen dort entlang aufweist, und wobei eine Befestigungskomponente durch einen der offenen Bereiche des röhrenförmigen Stützteils hindurchtreten.

21. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 20, dadurch gekennzeichnet, daß das röhrenförmige Stützteil (82; 121) eine Vielzahl von Drahtlitzen mit offenen Bereichen dazwischen aufweist.

22. Ein stützendes, endoluminales Implantat gemäß Anspruch 21, dadurch gekennzeichnet, daß die Drahtlitzen des röhrenförmigen Stützteils (82; 121) aus im allgemeinen sinusförmig konfiguriertem Draht bestehen, der schraubenförmig in das röhrenförmige Stützteil hinein gewunden ist, wobei der Draht dazwischen die offenen Bereiche des röhrenförmigen Stützteils definiert.

23. Ein stützendes, endoluminales Implantat gemäß Anspruch 21, dadurch gekennzeichnet, daß die Drahtlitzen der röhrenförmigen Stützteile als kreuzende, längliche Abschnitte geformt sind, welche integral miteinander sind, und dazwischen die Öffnungen definieren, um ein gitterförmiges, röhrenförmiges Stützteil zu bilden.

24. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 23, dadurch gekennzeichnet, daß das endoluminale Implantat eine Behandlungsoberfläche zur Biokompatibilität oder Medikamententherapie umfaßt.

25. Ein stützendes, endoluminales Implantat gemäß einem der Ansprüche 1 bis 24, dadurch gekennzeichnet, daß die Stammkomponente ein hervorstehendes Befestigungselement (130) beinhaltet.

26. Ein stützendes, endoluminales Implantat gemäß Anspruch 1, dadurch gekennzeichnet, daß die Stammkomponente (82 - 85) eine innere Oberfläche, eine äußere Oberfläche, welche nach außen hin von der inneren Oberfläche beabstandet ist und komplementär mit der inneren Oberfläche geformt ist, und ein Netzwerk von Stegbereichen mit dazwischen definierten offenen Bereichen aufweist,

wobei die Stammkomponenten-Auskleidung (83) eine dehnbare Wand ist aus im allgemeinen inertem, biokomplatiblem Material, wobei die dehnbare Wand an wenigstens eine der inneren Oberfläche und der äußeren Oberfläche des röhrenförmigen Stützteils angebracht ist, wobei die dehnbare Wand einen Dehnabschnitt aufweist, der sich über die röhrenförmige Stützkomponente davon erstreckt; und
wobei der Dehnabschnitt der dehnbaren Wand verzweigt ist in wenigstens zwei im allgemeinen röhrenförmige Beinabschnitte (85, 86) aus dehnbarem Wandmaterial, wobei jeder Beinbereich eine derartige Größe aufweist und derartig geformt ist, um eine der im allgemeinen zylindrischen, stützenden Beinkomponenten (89, 90) aufzunehmen.

27. Ein aufzweigendes, expandierbares, stützendes, endoluminales Implantat aus mehreren Komponenten wie in einem der vorhergehenden Ansprüche beansprucht, dadurch gekennzeichnet, daß die Stammauskleidung (122) an dem röhrenförmigen Stützteil (121) befestigt ist, und entlang seiner Länge eingeklemmt ist, und broschiert, genäht, und geklebt ist, um zwei verschiedene Beinabschnitte (109, 113) zu bilden.

Revendications

1. Greffon endoluminal de maintien expansible ramifié multicomposant comprenant :

plusieurs composants endoluminaux de maintien expansibles qui sont adaptés pour être déployés individuellement à un emplacement sélectionné à l'intérieur d'un vaisseau du corps, chacun desdits composants endoluminaux de maintien étant compressible radialement pour son insertion endoluminale et expansible radialement pour son déploiement à un emplacement désiré à l'intérieur d'un vaisseau du corps ;
l'un desdits composants endoluminaux de maintien expansibles étant un composant en tronc (82-85 ; 101), ledit composant en tronc comprenant un élément de maintien tubulaire (82 ; 121), au moins un autre desdits compo-

sants endoluminaux de maintien expansibles étant un composant en jambe de maintien généralement cylindrique (89, 90 ; 108, 115) ;

caractérisé en ce que ledit composant en tronc comprend une chemise de tronc (83 ; 122) positionnée le long dudit élément de maintien tubulaire, ladite chemise de tronc ayant une portion de corps généralement cylindrique (84 ; 123) et au moins deux portions de jambe (85, 86 ; 109, 113), chacune desdites portions de jambe définissant une ouverture de jambe (127, 128) ; et

ledit composant en jambe de maintien généralement cylindrique (89, 90 ; 108, 115) et l'une desdites portions de jambe (85, 86 ; 109, 113) du composant en tronc sont adaptés pour être positionnés de façon télescopique l'un par rapport à l'autre lorsque ledit composant en jambe et ledit composant en tronc sont déployés à l'intérieur du vaisseau de corps.

2. Greffon endoluminal de maintien selon la revendication 1, caractérisé en ce que ledit composant en jambe de maintien généralement cylindrique (89, 90 ; 108, 115) a une portion d'extrémité qui, à l'état déployé, est positionnée à l'intérieur de ladite ouverture de jambe (127, 128) du composant en tronc.

3. Greffon endoluminal de maintien selon la revendication 1 ou la revendication 2, caractérisé en ce que ladite pluralité de composants endcluminaux de maintien expansibles (82-85, 89, 90 ; 101, 109, 113) sont auto-expansibles.

4. Greffon endoluminal de maintien selon la revendication 1 ou la revendication 2, caractérisé en ce que lesdits plusieurs composants endoluminaux de maintien expansibles sont adaptés pour être déployés par un dispositif expansible radialement (69 ; 104, 107, 114).

5. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 4, caractérisé en ce que ledit composant en jambe de maintien généralement cylindrique comprend un élément support généralement cylindrique et une chemise généralement cylindrique qui est fixée le long de celui-ci.

6. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 5, caractérisé en ce que ladite chemise de tronc (83, 122) est une paroi extensible de matériau biocompatible essentiellement inerte, ladite paroi extensible étant fixée à une tortion de la surface interne de l'élément de maintien tubulaire à composant en tronc (82 ; 121) ladite paroi extensible ayant un diamètre qui se dilate avec ledit élément de maintien tubulaire à composant en tronc.

7. Greffon endoluminal de maintien selon la revendication 6, caractérisé en ce que ladite chemise du composant en jambe de maintien généralement cylindrique est une paroi extensible en matériau biocompatible essentiellement inerte, ladite paroi extensible étant appliquée sur au moins la surface interne de l'élément de maintien tubulaire généralement cylindrique du composant en jambe.

8. Greffon endoluminal de maintien selon l'une quelconque ces revendications 1 à 7, caractérisé en ce que lesdites portions de jambe (85, 86 ; 109, 113) de la chemise de tronc s'étendent longitudinalement au-delà dudit élément de maintien tubulaire du composant en tronc.

9. Greffon endoluminal de maintien selon la revendication 6, caractérisé en ce que lesdites portions de jambe sont séparées l'une de l'autre.

10. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 7, caractérisé en ce que lesdites cortions de jambe de la chemise de tronc sont généralement extensibles en longueur avec ledit élément de maintien tubulaire du composant en tronc.

11. Greffon endoluminal de maintien selon la revendication 11, caractérisé en ce qu'un tronçon extérieur (124, 125) de chacune desdites portions de jambe de la chemise de tronc (122) est fixé audit élément de maintien tubulaire (21) tandis que des tronçons intérieurs de chacune des portions de jambe sont fixés l'un à l'autre le long d'une couture interne (126).

12. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 11, caractérisé en ce que ledit composant en jambe de maintien généralement cylindrique (89, 90 ; 108, 115), lorsqu'il est déployé, est positionné à coulissement télescopique à l'intérieur de l'une des portions de jambe (85, 86 ; 109, 113) du composant en tronc.

13. Greffon endoluminal de maintien selon la revendication 5, caractérisé en ce que ladite chemise du composant en jambe et ladite chemise de tronc sont chacune une paroi extensible faite d'un matériau élastomère poreux qui fournit une structure permettant l'invasion cellulaire normale à l'intérieur d'elle-même à partir du vaisseau de corps lorsqu'elle est implantée à l'intérieur de celui-ci.

14. Greffon endoluminal de maintien selon la revendication 13, caractérisé en ce que ledit matériau élastomère poreux de chaque paroi extensible est un

polymère élastomère.

15. Greffon endoluminal de maintien selon la revendication 13, caractérisé en ce que ledit matériau élastomère poreux de ladite paroi extensible est un uréthanne polycarbonate.

16. Greffon endoluminal de maintien selon la revendication 13, caractérisé en ce que ledit matériau élastomère poreux est enrobé avec une fine couche de cacutchouc au silicone.

17. Greffon endoluminal de maintien selon la revendication 5, caractérisé en ce que ladite chemise de tronc et ladite chemise du composant en jambe sont chacune une paroi extensible le long de la surface interne et de la surface externe de chaque élément de maintien.

18. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 7 ou 13 à 17, caractérisé en ce qu'une extrémité longitudinale exposée dudit composant de maintien tubulaire s'étend longitudinalement au-delà de ladite chemise et n'est pas complètement couverte par celle-ci.

19. Greffon endoluminal de maintien selon la revendication 17, caractérisé en ce que ledit élément de maintien tubulaire a une pluralité de zones ouvertes le long de celui-ci, et ladite paroi extensible le long de ladite surface externe de l'élément de maintien tubulaire est collée à ladite paroi extensible le long de ladite surface interne de l'élément de maintien tubulaire en des emplacements définis par lesdites zones ouvertes de l'élément de maintien tubulaire.

20. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 19, dans lequel ledit élément de maintien tubulaire a une pluralité de zones ouvertes le long de celui-ci, et un composant de fixation traverse l'une desdites zones ouvertes dudit élément de maintien tubulaire.

21. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 20, caractérisé en ce que ledit élément de maintien tubulaire (82 ; 121) comprend une pluralité de torons de fil avec entre eux des zones ouvertes.

22. Greffon endoluminal de maintien selon la revendication 21, caractérisé en ce que lesdits torons de fil de l'élément de maintien tubulaire (82 ; 121) sont un fil configuré de façon généralement sinusoïdale qui est enroulé en hélice dans l'élément de maintien tubulaire, ledit fil définissant ainsi lesdites zones ouvertes de l'élément de maintien tubulaire.

23. Greffon endoluminal de maintien selon la revendication 21, caractérisé en ce que lesdits torons de fil de l'élément de maintien tubulaire sont conformés en longueurs allongées qui se coupent et qui sont solidaires l'une de l'autre et définissent entre elles lesdites ouvertures pour former un élément de maintien tubulaire maillé.

24. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 23, caractérisé en ce que le greffon endoluminal comprend un traitement de surface pour la biocompatibilité ou le traitement par médicament.

25. Greffon endoluminal de maintien selon l'une quelconque des revendications 1 à 24, caractérisé en ce que ledit composant en tronc comprend un élément de fixation dépassant (130).

26. Greffon endoluminal de maintien selon la revendication 1, caractérisé en ce que ledit composant en tronc (82-85) a une surface interne, une surface externe écartée vers l'extérieur de ladite surface interne et conformée de façon complémentaire avec celle-ci, et un réseau de zones pleines avec des zones ouvertes définies entre elles,

ladite chemise de composant en tronc (83) est une paroi extensible de matériau biocompatible essentiellement inerte, ladite paroi étant appliquée sur au moins l'une de ladite surface interne et de ladite surface externe de l'élément de maintien tubulaire, ladite paroi extensible ayant une portion d'extension qui s'étend au-delà dudit composant de maintien tubulaire ; et

ladite portion d'extension de paroi extensible est ramifiée en au moins deux portions de jambe généralement tubulaires (85, 86) en matériau de paroi extensible, chacune desdites portions de jambe étant dimensionnée et conformée pour recevoir ledit composant en jambe de maintien généralement cylindrique (89, 90).

27. Greffon endoluminal de maintien expansible ramifié multicomposant selon l'une quelconque des revendications précédentes, caractérisé en ce que ladite chemise en tronc (122) est fixée audit élément de maintien tubulaire (121) et est pincée le long de sa longueur et suturée, cousue et collée pour former deux portions de jambe distinctes (109, 113).

FIG. 1

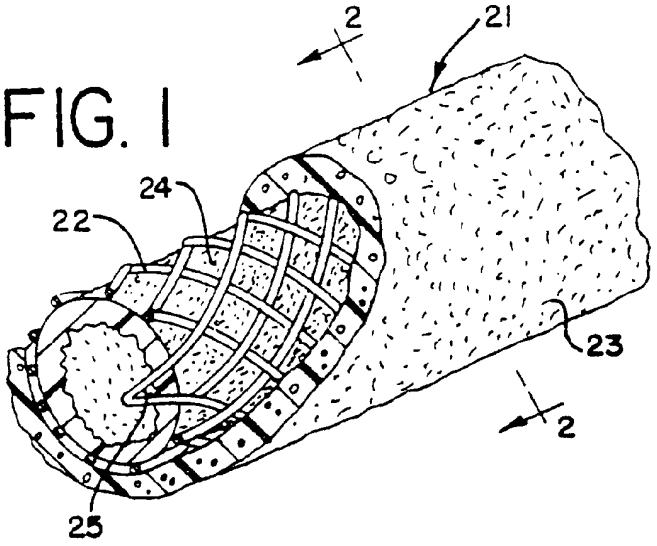


FIG. 2

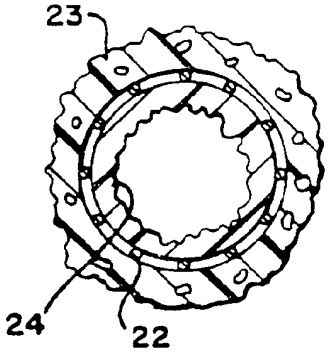
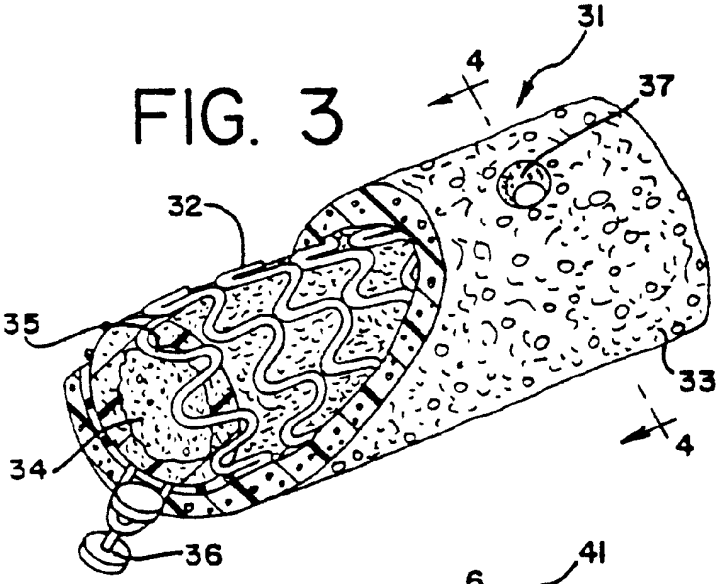


FIG. 3



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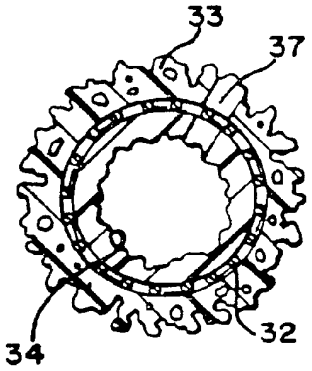

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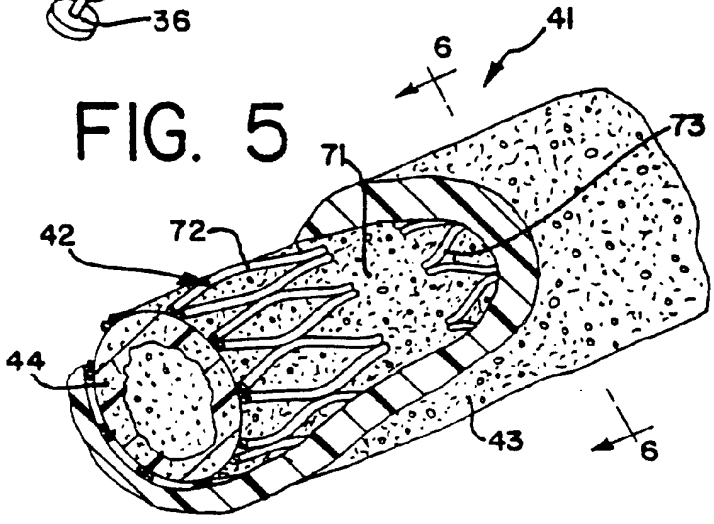

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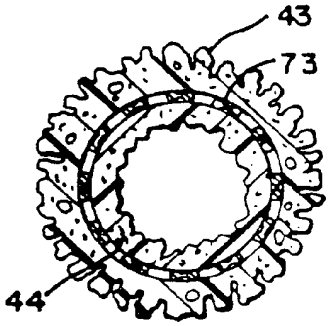

FIG. 7

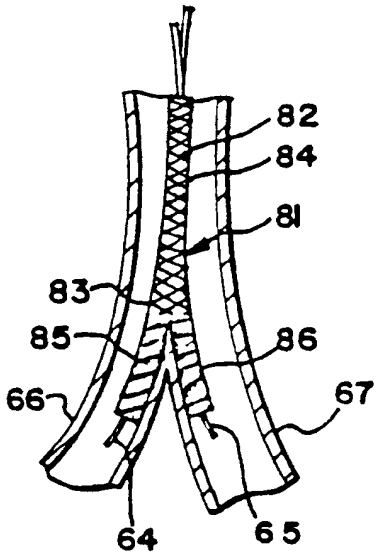

FIG. 8

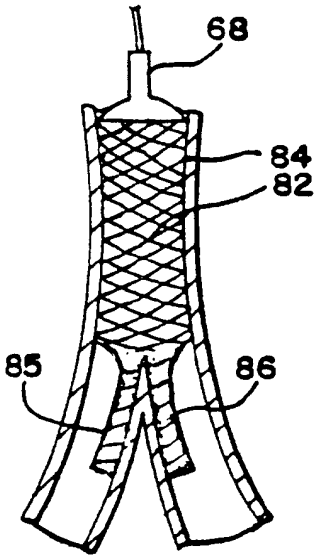

FIG. 9

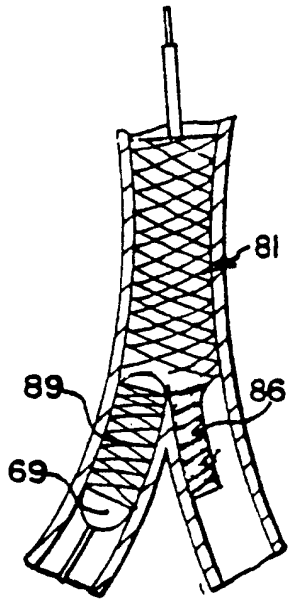

FIG. 10

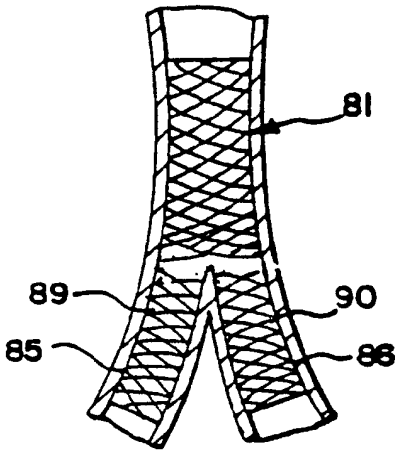

FIG. 11

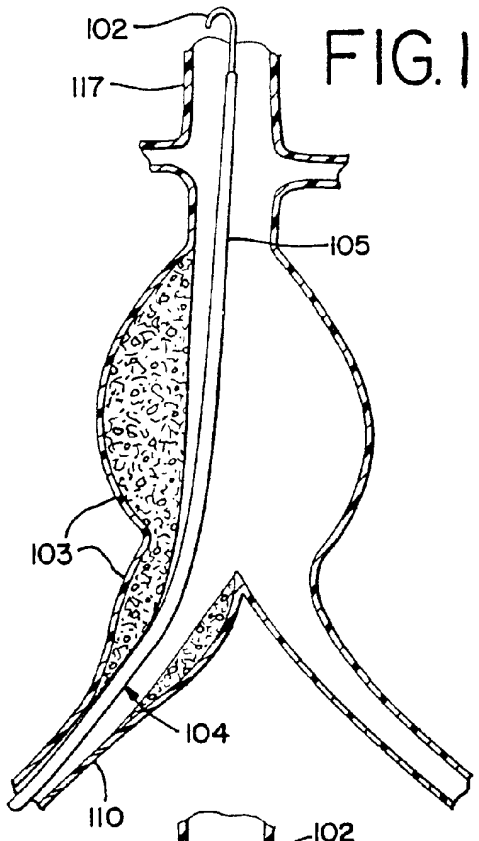

FIG. 12

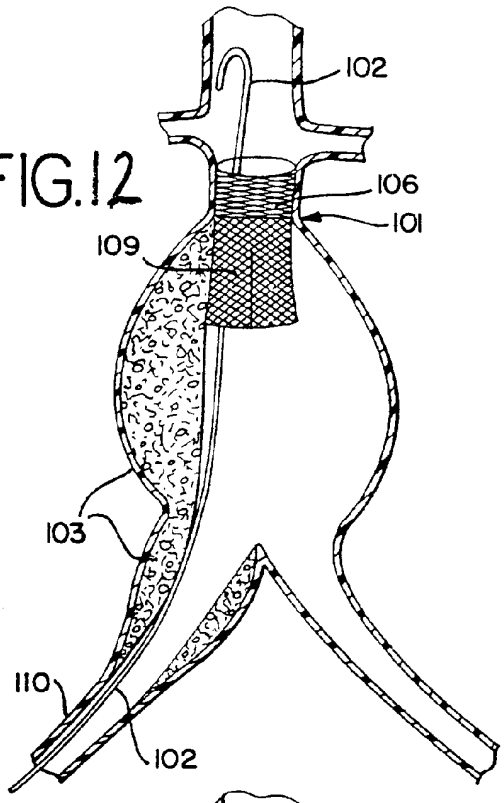

FIG. 13

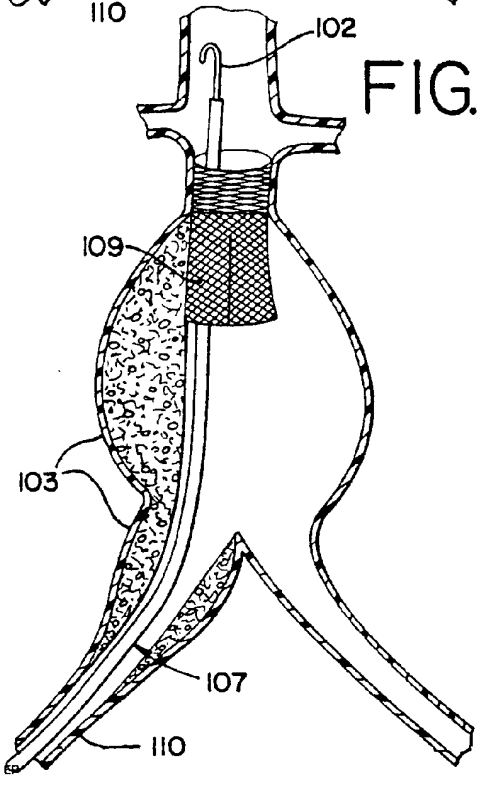

FIG. 14

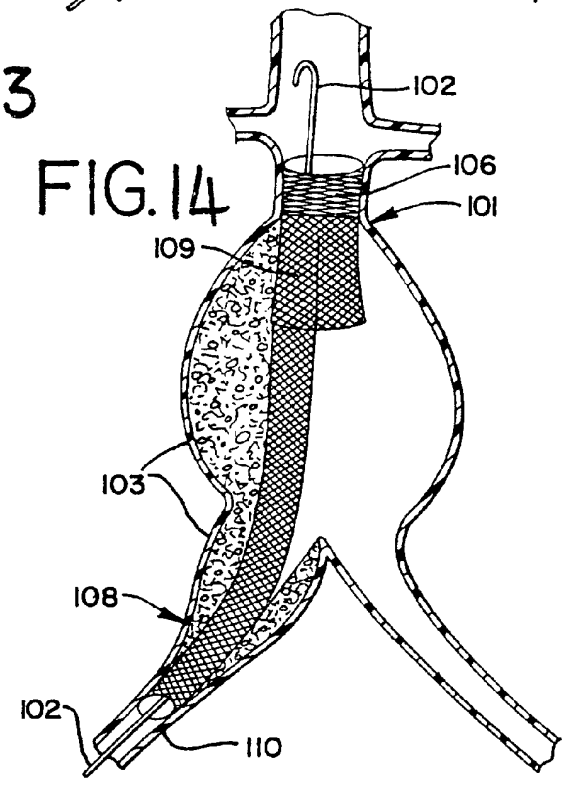

FIG. 15

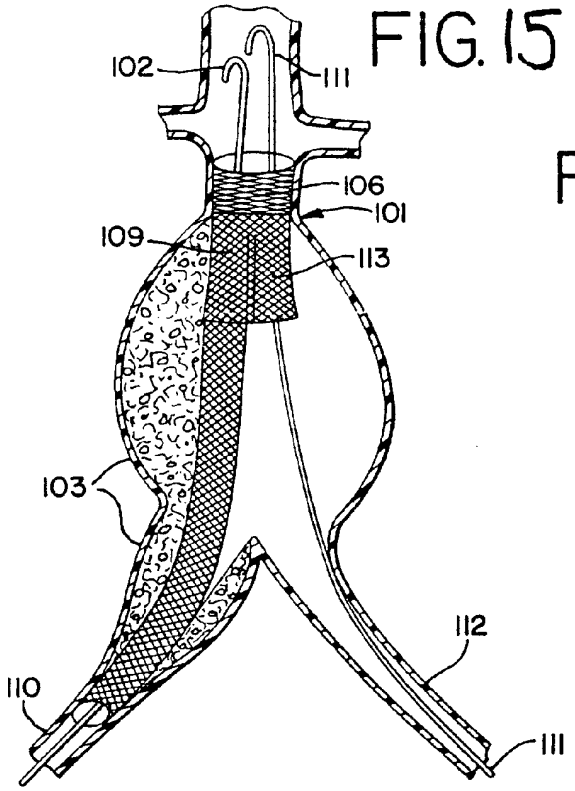

FIG. 16

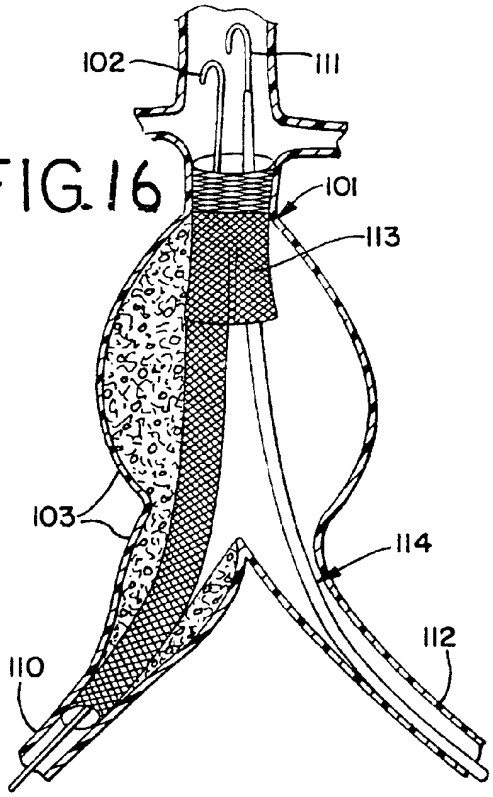

FIG. 17

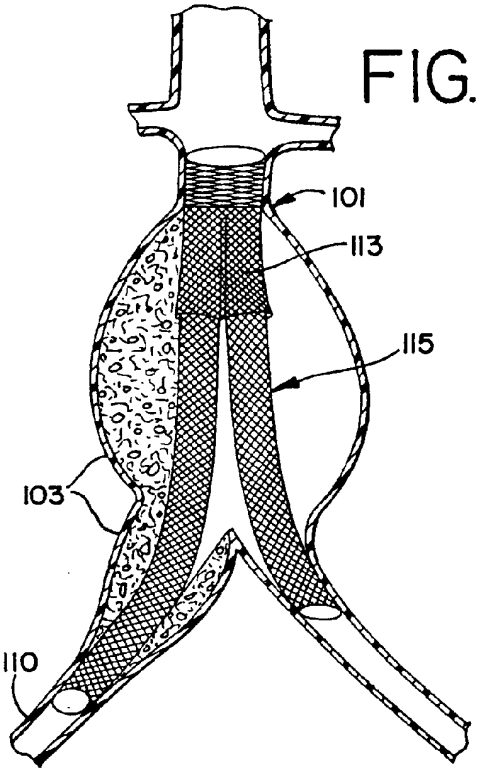

FIG. 18

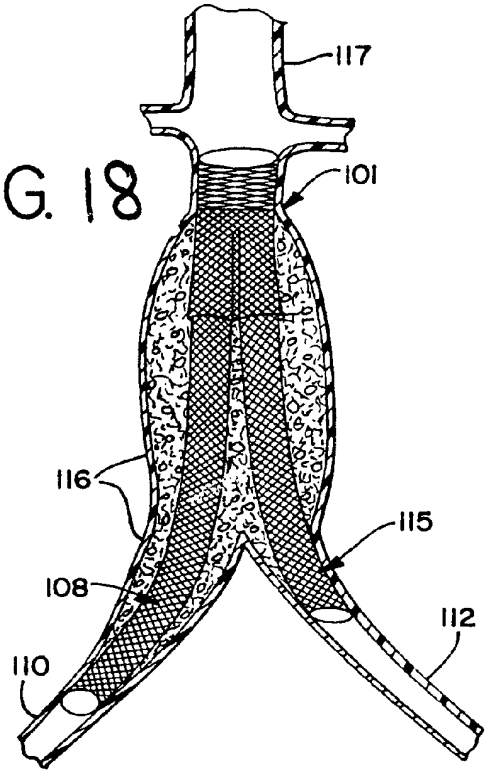

FIG. 19

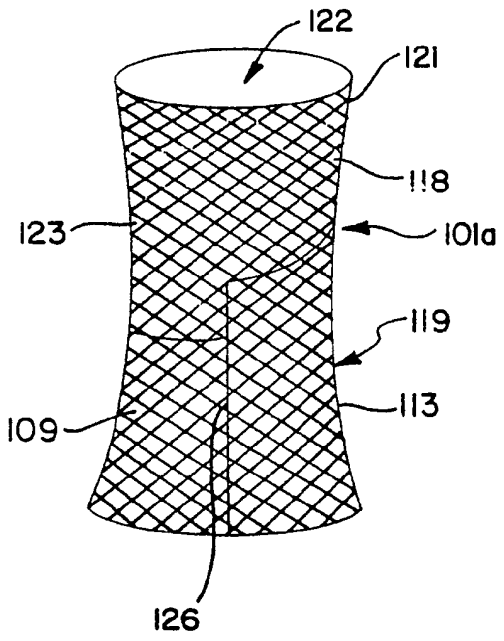

FIG. 20

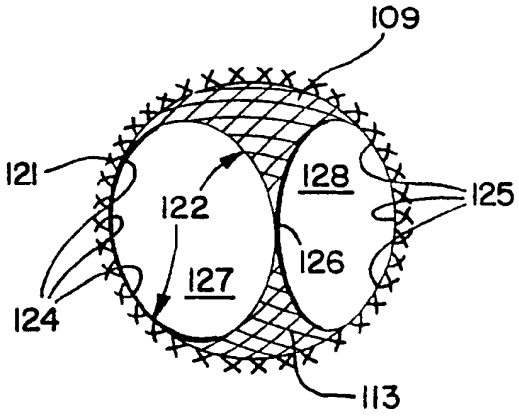

FIG. 21